

PATENT APPLICATION

PATENT AND TRADEMARK OFFICE

BEFORE THE HONORABLE BOARD OF PATENT APPEALS AND INTERFERENCES

In re the Application of

On Appeal from Group: 1600

Jerry Y. JONN et al.

Application No.: 09/919,877

Examiner: F. Choi

Filed: August 2, 2001

Docket No: 104226.01

For: ABSORBABLE ADHESIVE COMPOSITIONS

APPEAL BRIEF TRANSMITTAL

Commissioner for Patents
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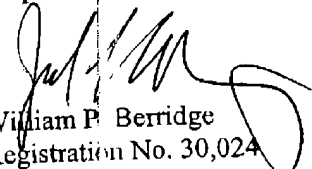
Sir:

Attached hereto are three (3) copies of our Brief on Appeal in the above-identified application. The attached Appeal Brief is a duplicate of the Appeal Brief originally filed on May 27, 2004.

The Brief fee in the amount of Three Hundred Thirty Dollars (\$330.00) in payment of the Brief fee under 37 C.F.R. 1.17(c) was originally paid by Check No. 154513 with the May 27, 2004, Appeal Brief Transmittal. In the event of any underpayment or overpayment, please debit or credit our Deposit Account No. 15-0461 as needed in order to effect proper filing of this Brief.

For the convenience of the Finance Division, two additional copies of this transmittal letter are attached.

Respectfully submitted,



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BRIEF ON APPEAL

Appeal from Group 1600

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Application No. 09/919,877

TABLE OF CONTENTS

	<u>Page</u>
I. INTRODUCTION	1
A. Real Party in Interest.....	1
B. Statement of Related Appeals and Interferences	1
C. Status of Claims.....	1
D. Status of Amendments.....	1
II. THE INVENTION.....	1
III. THE APPLIED REFERENCES	2
IV. ISSUES.....	3
V. GROUPING OF CLAIMS.....	3
VI. ARGUMENT.....	3
A. Factual Inquiries to Determine Obviousness/Non-Obviousness	3
B. The References Would Not Have Rendered Obvious the Claimed Invention.....	4
1. Clark Does Not Teach or Suggest the Claimed Invention	5
a. Clark Does Not Teach the Specific Claimed Alkyl Ester Cyanoacrylate.....	5
b. Clark Does Not Teach the Claimed Combination of Monomers	6
2. The Secondary References Fail to Overcome Clark's Deficiencies	7
3. Hammerslag Teaches Away from the Claimed Invention	9
C. Conclusion.....	10
VII. CONCLUSION.....	11
APPENDIX.....	A-1

Application No. 09/919,877

I. INTRODUCTION

This is an appeal from an Office Action mailed December 30, 2003, finally rejecting claims 1, 3-17 and 59-71 of the above-identified patent application. No claims are allowed.

A. Real Party in Interest

The real party in interest for this appeal and the present application is Closure Medical Corporation, by way of an Assignment recorded in the U.S. Patent and Trademark Office at Reel 012227, Frame 0268.

B. Statement of Related Appeals and Interferences

There are presently no appeals or interferences, known to Appellant, Appellant's representative, or the Assignee, which will directly affect or be directly affected by or have a bearing upon the Board's decision in the pending appeal.

C. Status of Claims

Claims 1, 3-27, 46, and 48-71 are pending. Claims 18-27, 46 and 48-58 are withdrawn from consideration. Claims 1, 3-17 and 59-71 are finally rejected and are on appeal. Claims 1, 3-27, 46, and 48-71 are set forth in the attached Appendix. Claims 1 and 59 are independent. Claims 3-17 and 68-71 directly or indirectly depend from claim 1; and claims 60-67 directly or indirectly depend from claim 59.

D. Status of Amendments

No Amendment After Final Rejection has been filed. Applicant requested reconsideration in response to the Final Office Action dated December 30, 2003, on March 29, 2004. By an Advisory Action dated April 19, 2004, it was indicated that the rejections were maintained.

II. THE INVENTION

The claimed invention is directed to biocompatible adhesive compositions, methods of treating tissue using such compositions, and kits containing such compositions. The

Application No. 09/919,877

invention is based in part on a subclass of cyanoacrylates, alkyl ester cyanoacrylates, that have been found to possess exceptional adhesive characteristics and additionally are minimally toxic to non-toxic as well as absorbable by living organisms. Page 3, lines 25-29. The invention utilizes a mixture or blend of the alkyl ester cyanoacrylate and a second, different monomer species, to provide different absorption and (non)-toxicity properties to the resultant polymer film. Page 4, lines 5-10. The combination thus allows for adjustment and tailoring of the degradation rate of the resultant formed polymer. Page 4, lines 11-13.

For example, Examples 5 and 6 of the application demonstrate the results provided when mixtures are made of two monomers, particularly butyl lactoyl cyanoacrylate (an alkyl ester cyanoacrylate) and 2-octyl alpha-cyanoacrylate. Example 5 demonstrates that the mixtures provide tailored setting characteristics, while Example 6 demonstrates that the mixtures provide tailored biodegradation rates. Pages 24-26. A benefit of such tailored biodegradation rates is that the compositions can be used in different methods to achieve different desired results.

More specifically, the claimed invention is directed to a biocompatible adhesive composition, comprising: a first monomer species; and a second monomer species different from said first monomer species, wherein at least said first monomer species is absorbable, and an absorption rate of said first monomer species is different from an absorption rate of said second monomer species, wherein said first monomer species comprises an alkyl ester cyanoacrylate. See claim 1.

III. THE APPLIED REFERENCES

The applied references are:

U.S. Patent No. 5,981,621 to Clark et al. (hereafter, "Clark");

U.S. Patent No. 3,995,641 to Kronenthal et al. (hereafter, "Kronenthal");

U.S. Patent No. 3,559,652 to Banitt (hereafter, "Banitt");

Application No. 09/919,877

J.A. Collins, et al., "Biological Substrates and Cure Rates of Cyanoacrylate Tissue Adhesives," Arch. Surg., Vol. 93(3), pp. 428-32 (1966) (hereafter, "Collins");

European Patent No. 0 965 623 (hereafter "EP 623"); and

U.S. Patent No. 6,386,203 to Hammerslag (hereafter, "Hammerslag").

IV. ISSUES

The only issue on appeal is whether claims 1, 3-17 and 59-71 would have been obvious under 35 U.S.C. §103(a) over Clark in view of Kronenthal, Banitt, Collins, and EP 623 and further in view of Hammerslag.

V. GROUPING OF CLAIMS

Each claim of this patent application is separately patentable, and upon issuance of a patent will be entitled to a separate presumption of validity under 35 U.S.C. §282. For convenience in handling of this appeal, all of the claims will be grouped and argued together, with claim 1 representative of the rejected claims. Thus, pursuant to 37 C.F.R. §1.192(c)(7), in this Appeal, the rejected claims stand or fall together.

VI. ARGUMENT

The Examiner rejects claims 1, 3-17 and 59-71 over Clark in view of Kronenthal, Banitt, Collins, and EP 623 and further in view of Hammerslag. However, in the rejection, the Examiner has consistently improperly applied the law relating to obviousness, and has failed to establish even a prima facie case of obviousness. Proper application of the law and consideration of the cited reference demonstrates that no prima facie case of obviousness has been shown.

A. Factual Inquiries to Determine Obviousness/Non-Obviousness

Several basic factual inquiries must be made in order to determine obviousness or non-obviousness of claims of a patent application under 35 U.S.C. §103. These factual inquiries are set forth in Graham v. John Deere Co., 383 U.S. 1, 17, 148 USPQ 459, 467 (1966):

Application No. 09/919,877

Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or non-obviousness of the subject matter is determined.

383 U.S. at 17-18, 148 USPQ at 467.

The specific factual inquiries set forth in Graham have not been considered or properly applied by the Examiner in formulating the rejection of the subject claims. Particularly, the scope and content of the prior art and the level of ordinary skill in the pertinent art were not properly determined and demonstrated and applied to the claimed invention.

In the present case, proper consideration of the factual inquiries demonstrates nonobviousness of the claimed invention. The cited reference does not teach or suggest the claimed biocompatible adhesive composition comprising different first and second monomer species, which have different absorption rates, and wherein the first monomer species comprises an alkyl ester cyanoacrylate.

B. The References Would Not Have Rendered Obvious the Claimed Invention

The claimed invention is generally directed to biocompatible adhesive compositions, methods of treating tissue using such compositions, and kits containing such compositions. In particular, claim 1 is directed to a biocompatible adhesive composition, comprising: a first monomer species; and a second monomer species different from said first monomer species, wherein at least said first monomer species is absorbable, an absorption rate of said first monomer species is different from an absorption rate of said second monomer species, and wherein said first monomer species comprises an alkyl ester cyanoacrylate.

Thus, independent claim 1 specifically requires the presence of an alkyl ester cyanoacrylate as the first monomer species, and a second monomer species that is different from the alkyl ester cyanoacrylate and has a different absorption rate. According to the claimed invention, the combination of a faster absorbing monomer species and non-absorbable (or less

Application No. 09/919,877

absorbable or slower absorbing) monomer species allows for adjustment and tailoring of the degradation rate of the resultant formed polymer. Example 6 in the specification, at pages 25-26, demonstrates that at varying percentages of two different polymerizable monomers, the biodegradation rate of the resultant polymer composition is varied.

Such a composition, and related methods and kits, were heretofore unknown in the art, and provides significant advantages for future uses.

1. Clark Does Not Teach or Suggest the Claimed Invention

Clark is directed to an applicator tip for dispensing a polymerizable and/or cross-linkable material which is porous, absorbent or adsorbent and includes a polymerization or cross-linking initiator. The initiator initiates polymerization or cross-linking when the polymerizable and/or cross-linkable material is dispensed through the applicator tip. The polymerizable and/or cross-linkable material may be applied to a variety of substrates. See Clark at Abstract.

The Examiner correctly points out that Clark discloses the use of various cyanoacrylate monomers. However, Clark nowhere specifically discloses, and entirely fails to teach or suggest, the particular use of alkyl ester cyanoacrylates, as specifically required by the claimed invention, much less in combination with a second, different monomer species that has an absorption rate that is different from the alkyl ester cyanoacrylate.

a. Clark Does Not Teach the Specific Claimed Alkyl Ester Cyanoacrylate

As described above, independent claim 1 specifically requires the presence of a first monomer species, which is an alkyl ester cyanoacrylate monomer. However, Clark nowhere teaches or suggests the specific claimed alkyl ester cyanoacrylate monomer, and thus cannot have rendered obvious the claimed invention.

Clark specifically discloses a number of suitable monomers, including specific suitable cyanoacrylate monomers, but fails to disclose the specific alkyl ester cyanoacrylates

Application No. 09/919,877

from within the generic group of cyanoacrylates. With respect to the monomers, Clark discloses that the monomers may suitably be selected from 1,1-disubstituted monomers of the formula $\text{CHR}=\text{CXY}$. See col. 4, lines 35-44. Clark goes on to disclose that preferred and "especially advantageous" monomers are the cyanoacrylates, including those of formula (II). See col. 4, line 52 to col. 5, line 12. At most, the disclosure of Clark only broadly encompasses the alkyl ester cyanoacrylates. However, alkyl ester cyanoacrylates are obtained from the broad disclosure of Clark only if the substituents R^3 , R^7 and R^8 are properly and narrowly selected from among their broad disclosed scope. Clark nowhere specifically teaches selecting each of R^3 , R^7 and R^8 in a manner to properly provide an alkyl ester cyanoacrylate, as claimed.

Still further, Clark discloses preferred monomers to include alkyl alpha-cyanoacrylates, such as 2-octyl cyanoacrylate. Col. 5, lines 33-39. Clark thus teaches away from selecting alkyl ester cyanoacrylates, from the broad monomer disclosure, and teaches that alkyl alpha-cyanoacrylates are instead preferred.

Accordingly, Clark does not disclose, teach or suggest specific examples of the alkyl ester cyanoacrylates. Nor does Clark teach or suggest any preference for one monomer over the rest, except perhaps for the use of alkyl alpha cyanoacrylates, and by no means discloses or suggests any preference for alkyl ester cyanoacrylates, which are not specifically disclosed in the reference. Although the disclosure of Clark may broadly encompass the various specific monomer components of the claimed invention individually, Clark would not have rendered obvious the claimed invention. The reference thus cannot have rendered obvious the claimed invention.

b. Clark Does Not Teach the Claimed Combination of Monomers

Still further, Clark nowhere teaches or suggests that any such specifically selected cyanoacrylate monomer should specifically be used in combination with a second, different

Application No. 09/919,877

monomer species, as claimed. Clark entirely fails to disclose the combined use of the two different monomer species, as claimed.

As described above, independent claim 1 specifically requires the presence of two different monomer species, one of which is the above-described alkyl ester cyanoacrylate monomer. However, Clark nowhere teaches or suggests the specific claimed combined use of an alkyl ester cyanoacrylate monomer and a second monomer species, and thus cannot have rendered obvious the claimed invention.

Just as Clark does not teach or suggest the required alkyl ester cyanoacrylate, so too does Clark fail to disclose, teach or suggest the combined use of two or more monomer species, having different absorption rates, in any combination, much less in the combination required by the present independent claims. Just as Clark does not teach or suggest any preference for one monomer over the rest, and does not teach or suggest the specific alkyl ester cyanoacrylates, so too does Clark not teach or suggest the use of two different monomer species having different absorption rates, as claimed.

In the present case, Clark fails to teach or suggest specifically selecting the alkyl ester cyanoacrylate monomer and a second, different monomer having a different absorption rate, as claimed. Clark only broadly encompasses the use of various cyanoacrylate monomers, but does not teach the combined use of two different monomers. In the absence of any such teachings, the reference cannot have rendered obvious the claimed invention.

2. The Secondary References Fail to Overcome Clark's Deficiencies

Furthermore, none of the secondary references, alone or in combination, overcome the above-described deficiencies of Clark, whether alone or in combination.

Kronenthal is cited for its disclosure of carbalkoxyalkyl 2-cyanoacrylates, which are disclosed to be readily assimilated by tissues and exhibit a relatively low degree of inflammatory tissue response. However, Kronenthal fails to disclose, teach or suggest that one

Application No. 09/919,877

of ordinary skill in the art should select two different monomer species, each having different absorption rates, for use in a biocompatible adhesive composition, as claimed. At most, one of ordinary skill in the art might have been motivated to modify Clark by using only the carbalkoxyalkyl 2-cyanoacrylate of Kronenthal. However, such a modification still would not have yielded the claimed invention. Any combination of Clark and Kronenthal would still thus not have included a mixture of two different monomer species, as claimed.

Banitt is cited for its disclosure of alkoxyalkyl 2-cyanoacrylates, which are disclosed to be biodegradable and of minimal toxicity. However, Banitt, like Kronenthal above, fails to disclose, teach or suggest that one of ordinary skill in the art should select two different monomer species, each having different absorption rates, for use in a biocompatible adhesive composition, as claimed. At most, one of ordinary skill in the art might have been motivated to modify Clark by using only the alkoxyalkyl 2-cyanoacrylate of Banitt. However, such a modification still would not have yielded the claimed invention. Any combination of Clark, Kronenthal and Banitt would still thus not have included a mixture of two different monomer species, as claimed.

Collins is cited for its disclosure that octyl 2-cyanoacrylate is a more effective tissue adhesive. Collins is further cited for its alleged teaching that a composition is desired having the low toxicity and fast polymerization rate of the higher homolog cyanoacrylates, and the biodegradability of methyl cyanoacrylate. However, Collins likewise fails to disclose, teach or suggest that one of ordinary skill in the art should select two different monomer species, each having different absorption rates, for use in a biocompatible adhesive composition, as claimed. In fact, when considered in combination with Clark, Kronenthal and Banitt, Clark and Collins appear to be directly contradictory to Kronenthal and Banitt. Each of Clark and Collins express a distinct preference for alkyl alpha-cyanoacrylates, whereas Kronenthal and Banitt express a preference for carbalkoxyalkyl 2-cyanoacrylate (Collins) or alkoxyalkyl 2-cyanoacrylates

Application No. 09/919,877

(Banitt). Accordingly, one of ordinary skill in the art would at best have been motivated to use either the monomers of Clark and/or Collins, or the monomers of Kronenthal or Banitt, but not a combination of them in a single composition. Any combination of the references thus would still not have provided the claimed invention.

In fact, Applicants submit that the contradictory teachings of Clark and Collins as compared to Kronenthal and Banitt, demonstrates that the asserted combination of the four references is improper. In order to combine the cited references, there must be some demonstrated motivation to do so, either in the references themselves or elsewhere in the art. However, no such motivation has been shown to combine the four cited references. Thus, the combination is both improper, and nevertheless does not provide the claimed invention.

EP 623 is cited for its disclosure of stabilizing agents, and thus is cited for limitations of dependent claims. However, this reference does not overcome the above-described deficiencies of the primary references as they relate to the independent claims. Accordingly, any combination of EP 623 with the remaining references would not have rendered obvious the claimed invention.

These secondary references thus fail to overcome the deficiencies of Clark, at least because none of the references, alone or in combination, teach or suggest the specific combination of monomers as claimed. One of ordinary skill in the art would not have combined the references in the manner asserted by the Examiner to practice the claimed invention.

3. Hammerslag Teaches Away from the Claimed Invention

Furthermore, the Examiner cites Hammerslag to support the rejection. However, any combination of Hammerslag with the remaining references is both improper, and would not have rendered obvious the claimed invention.

Application No. 09/919,877

The Examiner cites Hammerslag for the assertions that cyanoacrylates have varying biodegradation rates, and that the biodegradation rate of the cyanoacrylate can be altered as desired. However, while Hammerslag may teach biodegradation variation, Hammerslag in fact teaches away from the claimed invention.

The Examiner cites to Hammerslag at col. 5, lines 21-33 for the teaching of varying biodegradation. However, in that passage, Hammerslag only teaches that the biodegradation can be varied by cross-linking a polymer product into the cyanoacrylate adhesive. For example, Hammerslag teaches that biodegradation can be varied by cross-linking a polyacrylic acid having a molecular weight of 200,000-600,000 to the cyanoacrylate to form a final compound.

Nowhere does Hammerslag teach or suggest that the biodegradation rate could or should be varied by means of a biocompatible adhesive composition, comprising: a first monomer species and a second monomer species different from said first monomer species, wherein at least said first monomer species is absorbable, and an absorption rate of said first monomer species is different from an absorption rate of said second monomer species, and wherein said first monomer species comprises an alkyl ester cyanoacrylate, as claimed. Hammerslag does not teach or suggest that the biodegradation rate can be varied by using a mixture of two different monomer species, as claimed.

Because Hammerslag teaches incorporating a polymer product, rather than a second monomer species, into the composition to vary its biodegradation rate, Hammerslag actually teaches away from the claimed invention. Hammerslag does not teach or suggest that the biodegradation rate can be varied by using two different monomer species in the composition, as claimed.

C. Conclusion

Accordingly, considering the cited references in combination, one of ordinary skill in the art would not have been motivated to practice the claimed invention. The cited references fail

Application No. 09/919,877

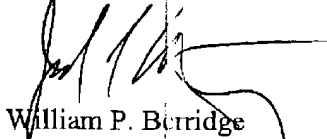
to teach or suggest selecting a plurality of different monomer species, having different absorption rates, where the first monomer species is an alkyl ester cyanoacrylate as claimed.

The claimed invention is thus patentable over the cited references.

VII. CONCLUSION

For all of the reasons discussed above, it is respectfully submitted that claims 1, 3-17 and 59-71 define patentable subject matter under 35 U.S.C. §103(a) over the cited reference, and are thus in condition for allowance. For all of the above reasons, Appellants respectfully request this Honorable Board to reverse the rejections of claims 1, 3-17 and 59-71.

Respectfully submitted,



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